ACT 28 S.B. NO. 2950

A Bill for an Act Relating to Generic Substitution of Prescription Drug Products.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. Section 328-1, Hawaii Revised Statutes, is amended by adding a new definition to be appropriately inserted and to read as follows:

"'"21 C.F.R." means Title 21, Code of Federal Regulations."

SECTION 2. Section 328-91, Hawaii Revised Statutes, is amended as follows:

1. By adding a new definition to be appropriately inserted and to read:

"'"United States Food and Drug Administration-approved generic drug product with therapeutic equivalency evaluations" means a generic drug product approved for marketing by the United States Food and Drug Administration pursuant to 21 C.F.R. part 314 and with established bioequivalency to the referenced brand drug pursuant to 21 C.F.R. part 320."

2. By amending the definitions of "compendia of therapeutically equivalent generic drugs" and "equivalent drug product" to read:

"'"Compendia of therapeutically equivalent generic [~~drugs"~~] drug products" means the Orange Book and any United States Food and Drug Administration documentation of any United States Food and Drug Administration-approved generic drug product with therapeutic equivalency[~~,~~] evaluations, including but not limited to:

(1) Letters of approval of Abbreviated New Drug Applications with therapeutic equivalency evaluations;
(2) Published listings of approved New Drug Applications or approved Abbreviated New Drug Applications with therapeutic equivalency evaluations; and
(3) Listings of first time generics with therapeutic equivalency evaluations, adopted by the [~~board.~~] director.

"Equivalent generic drug product" means a drug product with the same established name, active ingredient strength, quantity, and dosage form as the drug product identified in the prescription, and: (1) that is listed as therapeutically equivalent (i.e., addition) in the current [~~state drug formulary.~~] Hawaii additions and deletions list; or (2) that is listed in the compendia of therapeutically equivalent generic drug products and is not listed as therapeutically inequivalent (i.e., deletion) in the Hawaii additions and deletions list."

SECTION 3. Section 328-96, Hawaii Revised Statutes, is amended to read as follows:

"**§328-96 Drug formulary[.]; Hawaii additions and deletions list.** (a) The board may adopt rules, pursuant to chapter 91, to effectuate the purpose of this part. Without regard to chapter 91, the [~~board~~] director may adopt as rules the compendia of therapeutically equivalent generic [~~drugs~~] drug products as the state drug formulary of equivalent multiple source drug products. The board may adopt rules pursuant to chapter 91 to establish a Hawaii additions and deletions list[~~; provided that section 328-92(c) shall apply, and no pharmacist shall substitute an equivalent generic drug product for any prescription for an anti-epileptic drug to treat epilepsy, except upon the consent of the practitioner and the patient or the patient's parent or guardian~~]. Upon the adoption of the compendia of therapeutically equivalent generic [~~drugs~~] drug products by the [~~board,~~] director, the [~~board~~] department shall notify all pharmacies in the State and other interested individuals, within thirty working days, that the formulary has been updated. The Hawaii additions and deletions list may list additional substitutable drug products that are determined by the board to be safe, effective, and therapeutically equivalent. The Hawaii additions and deletions list may delete drug products listed in the compendia of therapeutically equivalent generic [~~drugs~~] drug products upon the board's finding that product quality or therapeutic equivalency or bioequivalency, as appropriate, is not adequately assured.

(b) Pursuant to chapter 91, the Hawaii additions and deletions list may be changed, added to, or deleted from as the board deems appropriate. Any person who requests that any change be made or that a drug product be included or added to or deleted from the Hawaii additions and deletions list shall have the burden of proof to show cause why the change, inclusion, addition, or deletion should be made.

(c) The board shall revise or supplement the Hawaii additions and deletions list as necessary.

(d) The department shall provide for distribution of the Hawaii additions and deletions list and its revisions and supplements, and the dissemination of notices of changes to the compendia of therapeutically equivalent generic [~~drugs,~~] drug products to all pharmacies in the State and to any other interested individuals. The department may establish fees to be charged to persons who receive the Hawaii additions and deletions list and its revisions and supplements, and notices of changes to the compendia of therapeutically equivalent generic [~~drugs.~~] drug products. The amounts of the fees charged shall be approximately the same as the costs of producing and distributing the Hawaii additions and deletions list and its revisions and supplements, and the notices of changes to the compendia of therapeutically equivalent generic [~~drugs.~~] drug products.

(e) Each pharmacy in the State shall:

(1) Maintain and update the compendia of therapeutically equivalent generic [~~drugs~~] drug products as it is approved by the [~~board;~~] director; and

(2) Obtain the Hawaii additions and deletions list.

(f) The department shall provide for public education regarding the provisions of this part and shall monitor the effects of this part."

SECTION 4. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

SECTION 5. This Act shall take effect upon its approval.

(Approved April 29, 2004.)